

REACH and the Challenge to the Leather Industry

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Abstract: REACH is the Regulation of the European Union (EU) on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007. REACH streamlines and improves the former legislative framework on chemicals in order to improve the protection of human health and the environment from the risks that can be posed by chemicals. This paper will not describe the whole legislation and their processes. The aim of this paper was to give background information and practical advice to the leather industry so as to maintain or establish business in and with Europe not only today but also in the REACH future.

Key words: EU; REACH; ECHA; DU; SIEF; SDS; RSL; SVHC; PBT; vPvB

1 Present status of REACH

The six-month REACH pre-registration period closed on 1st December 2008. A total of 65'655 companies submitted well over two million pre-registrations for approximately 143 000 substances to the EU Chemicals Agency (ECHA). This is fifteen times more pre-registrations than was expected by the legislative body.

Companies that have failed to pre-register cannot continue manufacturing in or importing their substance into the EU until they have submitted a full registration dossier. Tanneries as Downstream Users (DU) were normally not actively involved in this process, except those EU tanneries which are considered to be importers. Nevertheless, the EU tanners were active by making sure that tannery chemicals have not been forgotten to be pre-registered by their suppliers.

According to the definitions in the REACH Regulation, leather is an "article" and not a chemical "substance". However, there is an ongoing discussion regarding chemicals in articles. Chemical substances in articles, which will be intentionally released, should have been pre-registered. However, leather is an article, which does not intentionally release chemicals like a pen or an ink jet printer. This means leather is exempt from REACH registration.

The only new REACH requirement where articles are concerned is that certain so-called "substances of very high concern" are not allowed to be present in articles above 0.1%. This aspect is detailed in section 6 below.

2 The ongoing REACH procedure

ECHA has already announced the list of pre-registered substances. Tanneries can search this list for relevant chemical substances. However, in practise this is difficult as most leather chemical products are preparations made up of several chemical substances. The list is available at the following website address:

<http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx>

After the pre-registration step further REACH obligations must be fulfilled. The identified companies as importer and/or manufacturer must start data sharing in Substance Information Exchange Forums (SIEF). The important role of the active Lead Registrant is laid down by the REACH regulation and it is mandatory for each SIEF. The number of Lead registrants registered with ECHA has started very slowly and by the end of June 2009 was just over 500 (Tab. 1).

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Many European tanneries may be involved in this activity, too. The responsibility of an EU tannery as a Downstream User is to ensure that their suppliers are complying with the REACH regulation. The obligation of the manufacturer is to identify and to test his chemicals not only for the synthesis as such, but also for the use, e.g. the tanner should request that the supplier include the tannery uses in their chemical safety assessment. However, the supplier is not obliged to do this if he considers that particular use is not safe. In that case or for special uses or if the Downstream User will not disclose his application technique, then the Downstream User can perform the required chemical safety assessment test on his own behalf. However, most responsible chemical suppliers have already informed their tannery customers that they will be registering the substances in the chemicals they are supplying and including the tannery use in the chemical safety assessment.

Tab. 1 SIEF status (source ECHA)

Active Lead Registrants	
Date	Formed SIEF
24.06.2009	515
27.05.2009	293
22.04.2009	57

At the end, there will be a data set of all substances used in a tannery. This includes the quality and risk management to confirm the occupational safety and health regulation are observed. It is possible that over time a few chemicals will be withdrawn, or their uses restricted, but the suppliers will certainly do their best to offer alternatives.

With the implementation of REACH a tannery in Europe is only allowed to use chemicals which are considered and tested to use for leather manufacturing. As mentioned before, this work is normally conducted by the suppliers, who advise how the Downstream User should apply these chemicals safely. This information will be included in an attachment to the **Safety Data Sheets (SDS)** and will become available during the next years.

It may appear that with the implementation of REACH that the non EU tanneries will have some clear advantages compared with the EU leather producer because they are less restricted in choosing chemicals and they may avoid special expenditure for safety assessments. However this could be a serious misjudgement of the situation due to global trade in leather and leather chemicals. It is likely chemical suppliers will include such costs from REACH in their overhead costs and not assign them to products in different markets.

3 EU Export and Import data

Leather and leather articles are some of the most valuable consumer goods imported into Europe. Exports and imports play a major role for the EU consumer. Therefore, the global trade has to be considered by almost all non EU tanneries. They will be affected by REACH in a similar way to the EU tanneries. Even if the leather producers are not selling leather direct into Europe the article made from the leather is quite likely to be sold in the EU. The EU trade statistic shows the remarkable business volume in exports and imports (Tab. 2).

Tab. 2 EU external trade (source Eurostat)

EU-25 / 2005	Exports (€million)	Imports (€million)
Textile	23'121	95'794
Clothing	14'516	45'754
Leather and leather goods	12'123	19'576

The EU trade deficit may be explained by the rapidly increasing rate of imports from China and Vietnam during the last years. The import of leather and leather goods from China and Vietnam was more than 50% in 2005 (Tab. 3).

As an example: The overall EU shoe market was 2.5 billion pairs. Leather shoes covered 35 % of the total EU shoe market and the overall China shoe imports to EU was 1.25 billion pairs.

The REACH regulation will have an impact on leather or leather goods imported into Europe. Please remember that under today's EU regulations leather or leather goods containing restricted or banned chemicals cannot be imported into the EU. As a consequence not only the leather manufacturer in Europe but also the European leather importer must deliver leather that complies with the new REACH quality standards.

Tab. 3 Leather and leather goods (source Eurostat)

EU Imports 2005	Per cent
China	43.60
Vietnam	11.60
Romania	7.70
India	6.40
Brazil	3.65
Rest of the world	27.00

4 National and international regulation regarding chemicals

Global trade of chemicals is regulated by international agreements. The policy instruments that a country selects for national chemicals to respond to problems affecting its population and the quality of its environment may be quite different but they still comply with the international agreements. Already there are a lot of international agreements regarding production, transport, uses of chemicals, impact of man and environment, consumer welfare and finally the disposal of chemicals and their goods.

The selection of policy instruments has practical and resource implications. Some instruments utilized as part of existing national chemicals management schemes are relatively sophisticated in terms of technical capacity and resource needs, while other approaches though are perhaps less comprehensive. REACH is without doubt the leading chemicals management scheme. Although it is sophisticated, expensive and bureaucratic, it will provide more information regarding hazardous behaviour of chemical than we know today. In the future the EU will ban more substances under REACH and one can be sure that then they will also be banned under other international regulations.

5 Restricted Substances of International Brands and Retailers

The specifications of the international manufacturers, brand houses and retailers or their associations are often much more restrictive regarding unwanted chemical substances in their articles than some national regulations, such as REACH. They include substances from national regulation as well as many substances that considered being a public concern but are not controlled by regulation. These substances are all combined together in a so called **Restricted Substance List (RSL)**. Beyond doubt, REACH will

continue to be the reference point of most of the unwanted chemicals, as it was in the past with the old EU regulations.

6 REACH consequence

REACH has some key issues called authorisations and restrictions that need to be considered when making business with Europe. These very often now also include business with international manufacturers, brand houses or global retail companies. Kept in mind, these specifications can also apply to substances produced or imported in volumes below 1 tonne per year, which are exempt from REACH registration.

6.1 Authorisation: Annex 14 (XIV)

Substances of very high concern are subject to an authorisation procedure. EU Member States and the EU Chemicals Agency can place substances on the List of Substances of Very High Concern (SVHC). It is estimated by some experts that up to some 1500 substances could eventually be considered for inclusion in this list. On 28th October 2008 the EU Chemicals Agency started by including 15 substances in the SVHC Candidate List. Since this date (28th October 2008) the suppliers of articles that contain substances on the Candidate List above 0.1% must inform the customer and consumer to ensure safe use of the article and from 1st December 2011 the European Chemicals Agency (Tab. 4).

On 1st June 2009, taking into account the opinion of the ECHA's Member State Committee, the EU Chemicals Agency recommends that seven substances from the Candidate List should not be used without specific authorisation (Tab. 5). The prioritisation proposed was developed on the basis of the available information on intrinsic properties, uses, releases and volumes of the substances of very high concern on the Candidate List. Three of the recommended substances are classified as toxic to reproduction, one as carcinogenic and three fulfil the criteria for being Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB). They are all used in some products to which consumers and workers could be exposed.

Tab. 4 Substances of very high concern (SVHC)

Substances of very high concern (SVHC)
Carcinogens, mutagens or toxic to the reproductive system, categories 1 and 2
Substances which are persistent, bio-accumulative and toxic
Very persistent and very bio-accumulative
or of equivalent concern

Tab. 5 proposal of ECHA

Proposed substances for authorisation
Musk xylene (vPvB)
4,4'-diaminodiphenylmethane - MDA (carcinogenic)
Short chained chlorinated paraffins - SCCPs (PBT and vPvB)
Hexabromocyclododecane - HBCDD (PBT)
Bis(2-ethylhexyl)phthalate - DEHP (Toxic for reproduction)
Benzylbutylphthalate - BBP (Toxic for reproduction)
Dibutylphthalate - DBP (Toxic for reproduction)

If this proposal is agreed, these substances will be included in the SVHC list in Annex XIV of the REACH regulation. Companies who wish to continue to use these chemicals must apply for authorisation

to show that the risks posed by those substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. The aim of this procedure is to give industry the incentive to progressively substitute these substances with safer alternatives when technically and economically feasible.

6.2 Restriction: Annex 17 (XVII)

Restrictions are the safety net of the system. REACH places restrictions on the marketing and use of certain chemicals substances and preparations. Restrictions may be placed on chemicals when they are shown to cause harm to human health or to the environment. As shown in Tab. 6, the chemicals are restricted to protect:

Tab. 6 RECHA aim to protect

Safety use for

Workers

Consumers

The environment.

Annex 17 (XVII) of the REACH regulation contains a list of restricted chemicals with the associated restrictions and concentration limits. Any substance on its own, in a preparation or in an article may be subject to restrictions if it is use poses unacceptable risks to health or the environment. Restrictions can be imposed on the use of a substance in certain circumstances and products, the use by consumers or even on all uses, which is a complete ban of a substance.

All the existing EU Directives relating to chemical restrictions we transferred directly into the REACH regulation and it is these restrictions which are included in Annex 17. The tanner has been familiar with the restrictions of many EU Directives over the last years and they know that such chemicals are not allowed to be sold in the European market (Tab. 7).

Tab. 7 List of restricted substances

Restricted chemicals include:

Lead carbons

Lead sulphates

Benzene

Pentachlorophenol

Nonylphenol (and its ethoxylates)

Cadmium

Hexachloroethane

Creosote

Compounds containing mercury and arsenic

List of aromatic amines from azo dye component

List of azo dyes (with allergenic properties)

If a chemical substance is listed in annex 17 (XVII) one must not market or use any of these substances, or include them in preparations sold in Europe. In some cases the EU Directive applies to the consumer article, for example in the case of certain forbidden aromatic amines derived from the breakdown of azo dyes.

7 Conclusions

It is important that worldwide all tanneries cope with national and international regulations. This includes also the requirements of international manufacturers, brand houses and retailers. It is important than not only the EU tanneries but also the non EU tanneries should realise that they will need to cope with REACH in the coming years. Tanneries should always keep in close contact with their chemical suppliers and work together, if necessary to check alternatives to make sure that the leather continues to satisfy regulations such as REACH. This way the likelihood of any confiscation or restriction on the sale of leather and leather goods are unlikely. With this combined action we can ensure that the global trade complies with restrictions implemented by REACH. As well, we can protect the reputation of leather, leather goods and their manufacturer on a national and international basis.

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